

*A Workshop on*

# **Measurement Methods for Evaluation of the Reliability of Active Implantable Medical Devices**

**October 3–4, 2005**

**Lecture Room B  
Administration Building, Building 101  
National Institute of Standards and Technology  
Gaithersburg, MD 20899**

**Conference Chairperson**

**William F. Regnault  
U.S. Food and Drug Administration**

**Conference Co-chairperson**

**Elizabeth S. Drexler  
Materials Reliability Division  
National Institute of Standards and Technology**

**Conference Co-chairperson**

**John A. Tesk  
Biomedical Materials and Devices Consulting**

**Sponsored by:**

**US Food and Drug Administration (FDA)** <http://www.fda.gov/>  
**Center for Devices and Radiological Health** <http://www.fda.gov/cdrh/>  
**National Institute of Standards and Technology (NIST)** <http://www.nist.gov/>  
**Materials Science & Engineering Laboratory** <http://www.msel.nist.gov/>  
**Materials Reliability Division** <http://www.boulder.nist.gov/div853/>  
**Polymers Division** <http://polymers.msel.nist.gov/>  
**Manufacturing Engineering Laboratory** <http://www.mel.nist.gov/>

**With cooperation of: The American Society for Testing and Materials International (ASTM)**  
<http://www.astm.org/>

**Pre-registration is required, on-site registration is not available.  
To pre-register go to: [https://rproxy.nist.gov/CRS/conf\\_ext.cfm?conf\\_id=1485](https://rproxy.nist.gov/CRS/conf_ext.cfm?conf_id=1485)**

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## Agenda

### October 3, Day 1

8:00 AM	Registration & Continental Breakfast		
8:55 AM	<b>Introductions, Moderator, John A. Tesk</b>		
9:00 AM	Welcome to the Workshop, NIST & the FDA	Rich Kayser	NIST
9:10 AM	NIST & Biomaterials	Lori Henderson	NIST
9:20 AM	Introduction to the Workshop Issues	William F. Regnault	FDA

### **Plenary Sessions I, II & III Moderator, William F. Regnault, FDA**

09:35 AM	<b>Plenary Session I</b>		
09:35 AM	Patient Perceptions leading to Explantation	James Kane	FDA
10:00 AM	Post-Market Regulation of Medical Devices	Betty Collins	FDA
10:25 AM	GMP Regulations and Standards	Jan Welch	FDA
10:45 AM	<b>BREAK</b>		
11:00 AM	<b>Plenary Session II</b> – Designing for Intended Use and Reliability	Ali Mosleh	U MD
11:30 AM	<b>Plenary Session III</b> – MIL-STDS and Consensus Standards – Their Utility and their Inference for Device Reliability		
11:30 AM	What Standards are Needed?	Celeste Null	Intel
12:00 AM	Issues Surrounding the Use of Standards and Test Methods		Open Discussion
12:30 PM	<b>Lunch</b> , NIST Cafeteria		

### **Working Sessions I & II Moderator, Elizabeth Drexler, NIST**

01:30 PM	<b>Working Session I</b> –Plausible Mechanisms for Failure: Mechanisms inside the Can <i>Session Chair: Jack Martinez</i>		NIST
01:30 PM	Chip-level Design: Developments, Failure Mechanisms and Reliability Testing	Ken Rodbell	IBM
01:50 PM	Package-level Design: Developments, Failure Mechanisms and Reliability Testing	Robert Munroe (Retired)	Motorola
02:10 PM	Residual Gas Content and Ionic Content	Bob Thomas (Retired)	Rome AFB
02:30 PM	Answers for Advice that the Workshop Seeks (see Session Chair's Guide)		
03:30 PM	<b>BREAK</b>		
03:45 PM	<b>Working Session II</b> – Plausible Mechanisms for Failure: Mechanisms Outside the Can <i>Session Chair: Michael Schen</i>		NIST
03:45 PM	Corrosion Issues	Robert Baboian	RB Corrosion Service
04:05 PM	Impact, Trauma, and Vibration Issues	Dominick Hammerer	Med-El
04:25 PM	Answers for Advice that the Workshop Seeks (see Session Chair's Guide)		
05:25 PM	End of Day 1		

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## OCTOBER 4, DAY 2

7:45 AM Registration & Continental Breakfast

### 8:45 AM **Working Session III**

#### **Measurements for Accelerated Reliability Testing of Packages**

*Session Chair: Stan Purwin*

Johns Hopkins University

Applied Physics Laboratory

08:45 AM What are the Proper Accelerators for Predicting the Reliability of Active Implantable Medical Devices? Michael G. Pecht U MD

09:05 AM Answers for Advice that the Workshop Seeks (see Session Chair's Guide)

### 10:05 AM **BREAK**

### 10:20 AM **Working Session IV, Medical System Concerns- Manufacturers' Perspectives**

*Session Chair: Keith McLain*

Advanced Bionics Inc.

10:20 AM

David Erhart Medtronic

10:40 AM

Edmond Capcelea Cochlear Corporation

11:00 AM Answers for Advice that the Workshop Seeks (see Session Chair's Guide)

12:00 PM **Lunch**, NIST Cafeteria

### 01:00 PM **Session Chairs to Draft Workshop Summary**

### 01:00 PM **Working Session V, Reliability Issues for Future Devices**

*Session Chair: John Suehle*

NIST

(This session is open to all except the previous session chairs and presenters from their sessions who wish to work with their session chairs on developing Summary Recommendations)

### 02:15 PM **Conclusion and Summary Recommendations**

Who is to do what?

Where is the work to be done?

How is the work to be accomplished?

Is there a need for a follow-up workshop or symposium?

3:00 PM: **End of Workshop**

### **Planning Committee**

*William F. Regnault, Center for Devices and Radiological Health, FDA*

*Elizabeth S. Drexler, Materials Reliability Division, NIST*

*John A. Tesk, Consultant*

*Michael Schen, Advanced Technology Program, NIST*